K003952 1/2 MAR 1 6 2001

510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Índigo LaserOptic® Treatment System with Temperature Sensing Option.

Submitter: Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242
Telephone : 513-337-7987
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Contact Person : Jacquelyn A. Hughes, RAC

Device Name :

Trade Name:	Índigo LaserOptic® Treatment System
Common Name:	Diode laser with fiberoptic delivery system
Proprietary Name:	Índigo LaserOptic® Treatment System
Classification Name:	Laser-powered surgical instrument

Date Prepared: December 12, 2000

Predicate Device: The Índigo LaserOptic Treatment System with modified labeling is substantially equivalent to the current Índigo LaserOptic Treatment System cleared by FDA on December 23, 1997 (K963969), as well as the following previous submissions:

- K954195, cleared January 25, 1996, Índigo Portable Laser System Model IDL 830 and Índigo Fiberoptics
- K955758, cleared February 27, 1996, Índigo Portable Laser System with Temperature Feedback Model 830e
- K990851 Índigo Diffuser-Tip Fiberoptic with Temperature Sensing Option
- K960918, cleared October 8, 1996, VidaMed TUNA (Trans Urethral Needle Ablation) System

Device Description: The Índigo LaserOptic®Treatment System consists of two main components, the Indigo® 830e portable diode laser and the Diffuser-Tip Fiberoptic, which provide interstitial thermotherapy (ITT), or interstitial laser coagulation (ILC), for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH). This system was cleared for use in the treatment of BPH in premarket notification

K963969 and modifications to the Diffuser-Tip Fiberoptic were cleared in premarket notification K990851.

A third component of the system, the Bare-Tip Fiberoptic, was cleared in earlier premarket notifications, K954195 and K955758. These premarket notifications cleared the system for general surgery, urological surgery and gastroenterological procedures including the incision, excision, and ablation or coagulation of tissues with hemostasis and interstitial laser coagulation of soft tissues, such as tumors and fibroids.

Intended Use: The Índigo LaserOptic Treatment System is intended to be used as surgical instruments used in the non-contact mode to photocoagulate, vaporize/ablate soft tissue (muscle, connective tissue, organ), for cutting, excision, incision, and for coagulation of soft tissue in the contact mode (open/closed) surgical procedures. When used with bare fiberoptics, the Índigo diode laser can be used for the excision, of external tumors and lesions, complete and partial resection of internal organs, treatment of tumors and lesions, skin incision and tissue dissection and ablation. The Diffuser-Tip™ Fiberoptic is intended for the safe and effective treatment of Benign Prostatic Hyperplasia (BPH).

Comparison of Technological Characteristics: There has been no change to the technical or functional characteristics of the Índigo LaserOptic Treatment System. The modifications to the labeling included in this 510(k) are to incorporate the option of local anesthesia where clinically indicated. Clinical literature illustrates the successful use of the Índigo laser procedure with local anesthesia, as well as the Transurethral Needle Ablation (TUNA®) device, manufactured by VidaMed. The TUNA device has the same indication for BPH as the Índigo system.

While the devices are not identical in design or operating principle, both thermally treat the prostatic tissue to creat necrotic lesions. The TUNA System delivers low levels of RF energy at 460 kHz while monitoring tissue temperature to prevent damage to the surrounding tissues. When used with the Diffuser-Tip Fiberoptic, the Índigo LaserOptic Treatment System allows a controlled dose of laser energy to be delivered in wavelengths between 800 and 850 nanometers. This energy is diffused radially at 360° to the tissue. When the system is used in the tissue adaptive mode, the light diffusing section of the distal tip of the fiber permits temperature sensing of the tissue throughout the treatment duration. By monitoring tissue temperature in real time, the system automatically adapts heating to the specific tissue characteristics at each site to create comparable lesions at different sites and in different patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2001

Ms. Jacquelyn A. Hughes, RAC
Regulatory Affairs Manager
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K003952
Trade Name: Indigo LaserOptic® Treatment System
Regulatory Class: II
Product Code: GEX
Dated: December 20, 2000
Received: December 21, 2000

Dear Ms. Hughes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510 (k) Number (if known) : K003952

Device Name : Índigo LaserOptic® Treatment System

Indications for Use : The Índigo LaserOptic® Treatment System with Diffuser-Tip Fiberoptic is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 20-85cc and for general surgery, general urological and gastroenterological procedures including the incision, excision, and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissues.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-off)
Division of General Restorative Devices

510(k) number K003952

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)